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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/849,781	05/04/2001	Michael Snyder	6523-028	9891
20583	7590	07/31/2006	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			TRAN, MY CHAU T	
			ART UNIT	PAPER NUMBER

1639

DATE MAILED: 07/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/849,781

Applicant(s)

SNYDER ET AL.

Examiner

MY-CHAU T. TRAN

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 141, 164, 166, 169, 170, 173, 174, 177, 178, 181-186, 188 and 192-195 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 April 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/30/05</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1-16,93-101,106,107,112-133,138-159,162,164-167,169-171,173-175,177,178,181-186,188 and 192-195.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 12-16,93-101,106,107,112-133,138-140,142-159,162,165,167,171 and 175.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/01/2006 has been entered.

Application and Claims Status

2. Applicant's amendment and response filed 05/01/2006 are acknowledged and entered. Claims 1 and 192 have been amended. Claims 193-195 have been added.
3. The amendment filed on 11/04/2004: cancelled claims 108-110, 134-136, 160, 161, 163, 168, 172, 176, 179, and 180; amended claims 1, 5, 6, 93, 162, and 164-166; and added claims 181-192. The amendment filed on 01/21/2004: amended claims 1-10, 93, 108-109, and 134-135 and added claim 162-180. The amendment filed on 08/20/2003: cancelled claims 111, and 137 and added claims 160, and 161. The amendment filed on 4/10/03: cancelled claims 17-92, and 102-105.
4. Claims 1-16, 93-101, 106, 107, 112-133, 138-159, 162, 164-167, 169-171, 173-175, 177, 178, 181-186, 188, and 192-195 are pending.

Election/Restrictions

5. The instant species election requirement is still in effect as there is no allowable generic or linking claim. Applicant has elected the following species for the elected invention (Claims 1-16, 93-101, 106, 107, 112-133, 138-159, 162, 164-167, 169-171, 173-175, 177, 178, 181-186, 188, and 192) in the reply filed on 08/20/2003:

- a. For the single specific species of the plurality of proteins or molecules, applicant elected the plurality of proteins.
- b. For the single specific species of organism, applicant elected mammal.
- c. For the single specific species of biological activity, applicant elected kinase activity.
- d. For the single specific species of solid support, applicant elected glass slide.
- e. For the single specific species of interaction between the surface of the support and the substance, applicant elected covalently bound.
- f. For the single specific species of assaying reagent. This species is withdrawn in view of applicant argument filed 01/21/2004.
- g. For the single specific species of volumes of the wells, applicant elected the range between 1nl and 1 μ l. However, this election is moot with regard to the election of the solid support as being glass slide.
- h. For the single specific species of the bottoms shape of the wells, applicant elected round-shaped. However, this election is moot with regard to the election of the solid support as being glass slide.

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6. Claims 12-16, 93-101, 106, 107, 112-133, 138-140, 142-159, 162, 165, 167, 171, and 175 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to *nonelected species*, there being no allowable generic or linking claim. Applicant timely traversed the election requirement filed on 08/20/2003.

7. Claims 1-11, 141, 164, 166, 169, 170, 173, 174, 177, 178, 181-186, 188, and 192-195 are under consideration in this Office Action.

Priority

8. This instant application claims benefit to two provisional applications that are 60/201,921 filed on 5/4/2000, and 60/221,034 filed on 7/27/2000. This instant application is granted the benefit of priority for 60/201,921 and 60/221,034 under 35 U.S.C 119(e).

Information Disclosure Statement

9. The information disclosure statement (IDS) filed on 12/30/2005 has been reviewed, and the references that have been considered are initialed as recorded in PTO-1449 form(s).

Claim Objections

10. Claim 193 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 1 recites the limitation of "*the plurality of different*

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substances comprises 61 kinases or functional kinase domains thereof of an organism selected from the group consisting of a mammal, yeast, and Drosophila". Claim 193 recites the limitation of "*the different substances are kinases*", and this limitation does not further limit the subject matter of a previous claim 1. It is suggested that applicant amend claim 193 to recites the limitation of "*the different substances are 61 kinases*" in order to overcome this objection.

Claim Rejections - 35 USC § 112

11. Claims 1-11, 141, 164, 166, 169, 170, 173, 174, 177, 178, 181-186, 188, and 192-195 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The instant invention recites a product/apparatus, i.e. a positional addressable array. The product comprises a plurality of different substances on a solid support. Each different substance is at a different position on a solid support. The density of the different substances on a solid support is at least 100 different substances per cm². The plurality of different substances comprises 61 kinases or functional kinase domains thereof of an organism selected from the group of a mammal, yeast, and *Drosophila*.

With regard to the written description requirement, the attention of the Applicant is directed *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with

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reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed.

The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon “reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter.” *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985)(quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983)).

Additionally, it is noted that written description is legally distinct from enablement: “Although the two concepts are entwined, they are distinct and each is evaluated under separate legal criteria. The written description requirement, a question of fact, ensures that the inventor conveys to others that he or she had possession of the claimed invention; whereas, the enablement requirement, a question of law, ensures that the inventor conveys to others how to make and use the claimed invention.” See 1242 OG 169 (January 30, 2001) citing *University of California v. Eli Lilly & Co.* And also *In re Barker*, 559 F.2d 588, 194 USPQ 470 (CCPA 1977), cert. denied, 434 U.S. 1064 (1978); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1562, 19 USPQ2d 1111, 1115 (Fed. Cir. 1991).

In this case, the instant invention claimed product/apparatus comprises a broad genus of compositions, i.e. the claimed different substances that encompass any members of the protein kinase superfamily from the organism of ‘*mammal, yeast, or Drosophila*’, which represents enormous scope because the claims do not place any limitations on the number of atoms types of atoms or the way in which said atoms can be connected together to form such a compound and/or composition, i.e. the sequence similarity among the members of the claimed 61 different

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kinases or the shared structural motif of the claimed different functional kinase domains from the organism of '*mammal, yeast, or Drosophila*'. Thus, virtually an infinite number of possibilities would be included in Applicants' claimed scope encompassing virtually every known class and subclass of compounds. Although, the large protein kinase superfamily are well characterized and known in the art such that the sequences of any kinases from any mammal, yeast and *Drosophila* can be determine by bioinformatics tools and publicly available sequence information as evidence by Plowman et al. (*PNAS*, 11/23/1999, 96(24), pgs. 13603-13610; see pg. 13604, Table 1). However, within the large protein kinase superfamily there are various different homologous proteins, i.e. substantial variation within the genus. For example, Vanhaesebroeck et al. disclose a subfamily of protein kinase, i.e. phosphoinositide 3-kinase (PI3K), which have three distinct classes (see e.g. Abstract; pg. 241, fig. 2). In the class II PI3K, the large N-terminal shows no homology to any known protein and there are no indications for binding of these PI3Ks to adaptor proteins or Ras (see pg. 241, left col., line 31 thru right col. line 2), i.e. within the subfamily of PI3Ks there are structural variants that does not share a homology other than the catalytic subunit. Consequently, the scope of the instant claimed compositions, i.e. the claimed different substances encompass any members of the protein kinase superfamily from the organism of '*mammal, yeast, or Drosophila*', includes an enormous number of structural variants.

In contrast, the instant specification disclosures are directed to an array comprising a plurality of different proteins on a solid support (see specification: pg. 3, line 33 thru pg. 4, line 2; pg. 10, line 3 thru pg. 11, line 25). The instant specification one example is directed to an array comprising a plurality of different yeast protein kinase, specifically 122 different yeast

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protein kinases of the Ser/Thr and tyrosine kinase family members (see specification: example I, pg. 27, line 19 thru pg. 35, line 20; example II, pg. 41, line 19 thru pg. 43, line 6).

Applicants are referred to the discussion in *University of California v. Eli Lilly and Co.* (U.S. Court of Appeals Federal Circuit (CAFC) 43 USPQ2d 1398 7/22/1997 Decided July 22, 1997; No. 96-1175) regarding adequate disclosure. For adequate disclosure, like enablement, requires **representative examples**, which provide reasonable assurance to one skilled in the art that the compounds falling within the scope both possess the alleged utility and additionally demonstrate that *applicant had possession of the full scope of the claimed invention*. See *In re Riat* (CCPA 1964) 327 F2d 685, 140 USPQ 471; *In re Barr* (CCPA 1971) 444 F 2d 349, 151 USPQ 724 (for enablement) and *University of California v. Eli Lilly and Co* cited above (for disclosure). The more unpredictable the art the greater the showing required (e.g. by “representative examples”) for both enablement and adequate disclosure. In addition, when there is **substantial variation within the genus**, one must describe a sufficient variety of species to reflect the variation within the genus (e.g., see MPEP § 2163.05).

Here, the instant specification has only provided one working example of the claimed invention (i.e., the 122 different yeast protein kinases of the Ser/Thr and tyrosine kinase family members). Thus, a person of skill in the art would not believe that applicants were in possession of a genus that encompasses virtually an infinite number of compounds and/or compositions encompassing every class and subclass of the instant claimed protein kinase superfamily wherein there are an enormous number of structural variants.

Accordingly, applicants have not demonstrated in “full, clear, concise, and exact terms” that they are in possession of the claimed invention. The instant specification and claims do not

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provide any guidance as to what changes should be made to extend the instant specification one example to the infinite number of possibilities that are currently being claimed composition, i.e. the claimed different substances that encompass any members of the protein kinase superfamily from the organism of '*mammal, yeast, or Drosophila*', for the instant claimed array. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variable, the instant specification single example is insufficient to describe the enormous genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. In *Fiddes v. Baird*, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

In the present instance, the specification does not teach claimed array comprising different substances that encompass any members of the protein kinase superfamily from the

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organism of 'mammal, yeast, or *Drosophila*'. Therefore, only the 122 different yeast protein kinases of the Ser/Thr and tyrosine kinase family members, but not the full breadth of the claim method meet the written description provision of 35 U.S.C 112, first paragraph.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 1-11, 141, 181-186, 188, and 192-195 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner et al. (US Patent 6,329,209 B1) and Ashmarina et al. (*Eur. J. Biochem.*, 1985, 149(1), pgs. 67-72).

The instant invention recites a product/apparatus, i.e. a positional addressable array. The product comprises a plurality of different substances on a solid support. Each different substance is at a different position on a solid support. The density of the different substances on a

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solid support is at least 100 different substances per cm². The plurality of different substances comprises 61 kinases or functional kinases domains thereof of an organism selected from the group of a mammal, yeast, and Drosophila.

Wagner et al. disclose arrays of protein-capture agents and the methods of making and using the arrays (see e.g. Abstract; col. 2, line 58 thru col. 3, line 9; col. 3, line 17-31; col. 3, line 58 thru col. 4, line 2). The array comprises a substrate (refers to instant claimed solid support), and a plurality of patches arranged in discrete, known regions on the substrate surface wherein a plurality of different protein-capture agents (refers to instant claimed a plurality of different substances) are immobilized on the patches of the array (see e.g. col. 2, line 58 thru col. 3, line 9; col. 9, line 58 thru col. 10, line 15; col. 10, lines 60-64). The array comprises 100 or more patches within a total area of about 1cm² or less on the surface of the substrate wherein each patches comprises a different protein-capture agent, i.e. 100 different protein-capture agent per cm² (refers to instant claimed limitation of “*the density of the different substances on a solid support is at least 100 different substances per cm²”* and instant claims 2-10)(see e.g. col. 10, lines 23-32 and 47-59; col. 11, lines 1-11 and 28-56). The substrate comprises a flat surface and composes of material such as metal or glass (refers to instant claim 11 and the elected species of substrate, i.e. glass slide)(see e.g. col. 13, line 48 thru col. 14, line 14). The patches comprise an organic thinfilm on which the protein-capture agents are immobilized (see e.g. col. 9, line 66 thru col. 10, line 5; col. 15, lines 25-30). The organic thinfilm comprises molecules of the formula X-R-Y, wherein X is a functional group that binds R to the surface, R is a spacer, and Y is a functional group for binding protein-capture agents (see e.g. col. 15, lines 47-53; col. 17, line 19 thru col. 50). On type of organic thinfilm comprises X is a trialkoxysilane, R is a linear hydrocarbon with an interrupting —O—, and Y is an epoxy (refers to instant claim 141). The

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protein-capture agent comprises naturally occurring, recombinant, or synthetic biomolecule such as protein or polynucleotide (see e.g. col. 4, lines 48-67; col. 5, lines 16-33).

The array of Wagner et al. differs from the presently claimed invention by failing to disclose that the protein-capture agents are yeast kinases.

Ashmarina et al. disclose immobilizing yeast phosphoglycerate kinase to screen for specific activity of monomeric enzyme (see e.g. Abstract; pg. 68, right col., lines 30-40; pg. 69, fig. 2). The yeast phosphoglycerate kinase is immobilized onto a polymer substrate (see e.g. pg. 68, left col., lines 27-36; pg. 68, right col., lines 30-40; pg. 69, fig. 2).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose that the protein-capture agents are yeast kinases as taught by Ashmarina et al. in the array of Wagner et al. One of ordinary skill in the art would have been motivated to disclose that the protein-capture agents are yeast kinase in the array of Wagner et al. for the advantage of providing a method of screening specific activity of monomeric enzyme (Ashmarina: pg. 67, right col., lines 15-22) since both Wagner et al. and Ashmarina et al. disclose immobilizing protein onto a polymer substrate (Wagner: col. 15, lines 33-47; Ashmarina: pg. 68, left col., lines 27-36). Moreover, Wagner et al. disclose that the protein-capture agents can be any molecules or complex of molecules that has the ability to bind a protein can be use (Wagner: col. 12, lines 45-48) and thus the type of substance immobilized on the surface of the substrate would be a choice of experimental design and is considered within the purview of the cited prior art. In addition, the specific type of kinase or functional kinase domains as claimed in claims 194 and 195 would be a choice of experimental design and is considered within the purview of the cited prior art.

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Furthermore, one of ordinary skill in the art would have a reasonable expectation of success in the combination of Wagner et al. and Ashmarina et al. because Ashmarina et al. illustrate by example the success of immobilizing yeast kinase onto a polymer substrate (Ashmarina: pg. 69, Table 1).

Therefore, the combine teachings of Wagner et al. and Ashmarina et al. do render the array of the instant claims *prima facie* obvious.

Status of Claim(s) Objection(s) and/or Rejection(s)

15. Applicant's arguments, see page 22, filed 05/01/2006, with respect to the rejection of claims 1-11, 141, 164, 166, 169, 170, 173, 177, 178, 181-186, 188, and 192 (*Note: Claims 187 and 189-191 are cancelled*) under 35 USC 112, first paragraph (written description rejection regarding the limitation of kinases are derived from *any* mammal or *any* Drosophila) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Vanhaesebroeck et al. (*Experimental Cell Research*, 11/25/1999, 253(1), pgs. 239-254).

16. The rejection of claims 1-11, 141, 164, 166, 169, 170, 173, 177, 178, 181-186, 188, and 192 (*Note: Claims 187 and 189-191 are cancelled*) under 35 USC 112, first paragraph (written description rejection regarding the limitation of "*molecules comprising functional domains thereof*") has been withdrawn in light of applicant's amendments of claim 1 wherein the limitation of "*molecules comprising functional domains thereof*" has been amended to recite the limitation of "*functional kinase domains thereof*".

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 571-272-0810. The examiner can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, Jr., can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

My-Chau T. Tran
July 23, 2006

